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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/542,577 | 07/19/2005 | Takanori Uchida | UCHIDA9 | 6886 |

1444 7590 01/17/2008

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

| EXAMINER | |
|---|---|
| KIM, TAEYOON | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 01/17/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/542,577 | UCHIDA ET AL. | |
| | Examiner | Art Unit | |
| | Taeyoon Kim | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,5,6,14,17-21,24-29 and 32-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,14,17-21,24-29 and 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/2007 has been entered.

Claims 2-4, 7-13, 15, 16, 22, 23, 30 and 31 have been canceled, and claims 1, 5, 6, 14, 17-21, 24-29 and 32-35 are pending and have been considered on the merits. All arguments have been fully considered.

### *Response to Arguments*

In the response to the previous office action mailed on 6/1/2007, applicant argued that PTO acknowledged that Greenawalt does not teach a process of "forming the nonwoven fabric comprising thrombin and fibrinogen, wherein the fabric being treated with thrombin first and then treated with fibrinogen..." and further asserting there is any reason provided by the "prior art" to be obvious to do so. This argument is not persuasive. First of all, the limitation in question is the order of process step for treating thrombin first and then fibrinogen to the fabric. The previous office action clearly cited M.P.E.P. §2144 for the prior legal decision for the rationale used by the court. Therefore, the prior art (Greenawalt et al.) does not need to provide any reason for the rejection.

Applicant further asserted that Greenawalt does not lead the person of ordinary skill in the art to the use of a PGA nonwoven fabric as a supporting material. This argument is not persuasive because Greenawalt clearly discloses PGA as an example of biopolymer used for the hemostatic composition (see column 9, lines 7-8; Examples 6, 7, 14, 15 and 17). Furthermore, Greenawalt clearly teach the composition being made in non-aqueous solvent (not in water) and therefore thrombin does not activate fibrinogen during processing (see column 8, lines 57-60; column 15, claim 1).

Further, applicant argued that paper-making technology utilized by the reference is different from the current invention since the current invention utilizes needle-punching piled woven or knitted fabric into nonwoven fabric as shown in Japanese Patent publication No. 18579/1993 filed by Gunze Limited. The examiner respectfully points out that the current invention does not claim such process or process steps. The independent process claim (claim 14) discloses a method of preparing bioabsorbable synthetic nonwoven fabric holding thrombin and fibrinogen comprising steps of immersing the fabric of PGA into thrombin solution and lyophilizing, and then applying fibrinogen to the fabric containing thrombin before use thereof, or sequentially spraying thrombin and fibrinogen onto a bioabsorbable synthetic nonwoven PGA fabric.

Nevertheless, due to the current amendment, the argument is considered to be moot and the previous claim rejection has been withdrawn. However, these claims are now rejected under a new ground (see below).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 6, 21, 24-28 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenawalt et al. (US 6,056,970) in light of Ikada et al. (US 4,882,162).

Claims 1, 5, 6, 21, 24-28 and 32-35 are drawn to a hemostatic material or a kit comprising thrombin and fibrinogen on a bioabsorbable synthetic nonwoven fabric of polyglycolic acid (PGA); a limitation to the hemostatic material or kit comprising an additive selected from Factor XIII, a protease inhibitor, or calcium chloride; the additive being Factor XIII in a container comprising fibrinogen; a limitation to thrombin and fibrinogen being derived from human blood or produced by a genetic recombinant technique; a hemostatic kit comprising a bioabsorbable synthetic nonwoven fabric holding thrombin and a container comprising fibrinogen; a limitation to the hemostatic

material being in the form of sheet having sufficient flexibility and elasticity to stick area with any shape.

Greenawalt et al. teach a composition and a kit comprising hemostatic compounds such as thrombin, fibrinogen, Factor XIII, protease inhibitors and calcium chloride, along with a bioabsorbable synthetic polymer (nonwoven fabric) made of polyglycolide (polyglycolic acid; PGA)(columns 2-4).

Greenawalt et al. also teach thrombin and fibrinogen are derived from human plasma or synthetic forms produce by recombinant DNA technology (column 3, lines 52-64).

Greenawalt et al. also teach the PGA containing thrombin by mixing thrombin and PGA in organic solvent and then drying (lyophilizing) the combination (see Example 17).

Although the composition comprising PGA/thrombin described above does not contain fibrinogen, it is well known in the art that activation of fibrinogen to fibrin by thrombin is required for hemostatic material, and Greenawalt et al. teach a two component system of fibrin glue, which comprises thrombin and fibrinogen separately and used together prior to application (see column 1, lines 19-38). Therefore, it would have been obvious to a person of ordinary skill in the art to add fibrinogen in the PGA/thrombin composition of Greenawalt et al. at the time of using the hemostatic composition for stopping bleeding and/or sealing wounds. By the combining fibrinogen to the PGA/thrombin of Greenaswalt et al., the limitation of step (1) of claim 14 is inherently met by the reference.

Greenawalt et al. teach a hemostatic kit containing multiple hemostatic compositions in a separate package (column 6, lines 51-55).

Greenawalt et al. also teach the composition can include other components to provide stability, strength and flexibility (see column 15, lines 25-27).

With regard to the limitation in claim 28, the claim contains a product-by-process limitation.

M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-

process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

With regard to the limitation to the hemostatic kit wherein Factor XIII being included in a container comprising fibrinogen, although Greenawalt et al. teach Factor XIII being an additional component in the hemostatic composition, and a hemostatic kit comprising multiple hemostatic component in a separate package (see column 6, lines 53-55), the reference does not specifically teach factor XIII being in a container comprising fibrinogen. Greenawalt et al. disclose that Tisseel™ comprises two components, and one of which is fibrinogen component including factor XIII (see column 1, lines 26-28). Therefore, it would have been obvious to a person of ordinary skill in the art to add Factor XIII in a container comprising fibrinogen in order to prevent fibrinolysis.

Although Greenawalt et al's product is described as "paper-like material," it is made of PGA (see Example 17), which would provide sufficient elasticity and flexibility as evidenced by Ikada et al. (see column 3, lines 51-65). Therefore, the PGA fabric of

Greenawalt et al. would have inherent elasticity and flexibility to be formed into any shape. Unless applicant provides clear evidence that the composition of Greenawalt et al. does not possess the same elasticity and flexibility of the claimed invention, the examiner takes the position that the product of Greenawalt et al. would have the same property as the current invention.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made especially in the absence of evidence to the contrary.

Claims 1, 5, 6, 14, 17-21, 24-29 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugitachi et al. (US 4,265,233) in view of Roth (US 3,937,223) in further view of Greenawalt et al. (supra).

Claims 1, 5, 6, 14, 17-21, 24-29 and 32-35 are drawn to a hemostatic material or a kit comprising thrombin and fibrinogen on a bioabsorbable synthetic nonwoven fabric of polyglycolic acid (PGA); a limitation to the hemostatic material or kit comprising an additive selected from Factor XIII, a protease inhibitor, or calcium chloride; the additive being Factor XIII in a container comprising fibrinogen; a limitation to thrombin and fibrinogen being derived from human blood or produced by a genetic recombinant technique; a method of preparing a bioabsorbable synthetic nonwoven fabric made of PGA by the steps of immersing a bioabsorbable synthetic nonwoven fabric into a solution containing thrombin and lyophilizing the obtained nonwoven fabric, and then applying fibrinogen before use thereof, or sequentially spraying thrombin and fibrinogen

onto the PGA fabric; a hemostatic kit comprising a bioabsorbable synthetic nonwoven fabric holding thrombin being made by the method; a limitation to the hemostatic material being in the form of sheet having sufficient flexibility and elasticity to stick area with any shape.

Sugitachi et al. teach an absorbable material such as polyglycolic acid comprising thrombin, and a process of making such is by dipping the material in saline solution of thrombin and then lyophilized (see Examples 2 and 6).

Sugitachi et al. do not teach the absorbable material being non-woven fabric.

Roth teaches a hemostatic felt made of PGA (see Abstract). Roth also teaches PGA felt (non-woven fabric) having flexibility to conform readily to the surface of a bleeding wound (see Abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the absorbable material of Sugitachi et al. with the PGA felt of Roth.

The skilled artisan would have been motivated to make such a modification because the PGA felt of Roth is considered as an art-accepted equivalent for the same purpose of stopping bleeding and/or wound healing as the absorbable material taught by Sugitachi et al., which would be made of the same material, PGA.

M.P.E.P. §2144.06 states "In re Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core

of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.)."

Although Sugitachi et al. in view of Roth do not teach the material comprising fibrinogen, it would have been obvious to a person of ordinary skill in the art to use fibrinogen separately or together with thrombin/PGA fibers of Sugitachi et al. in view of Roth, because it is notoriously well known in the art that the role of thrombin is to activate fibrinogen to fibrin to form a fibrin network, and fibrinogen is commonly added to thrombin or visa versa. For example, a fibrin sealant, Tisseel™, disclosed by Greenawalt et al. comprises two-component system: fibrinogen component and thrombin component, and fibrinogen component comprising Factor XIII, to be mixed before the use the system (see column 1, lines 20-30). Thus, a person of ordinary skill

in the art would recognize that additional fibrinogen comprising Factor XIII taught by Greenawalt et al. applied to the thrombin/PGA felt of Sugitachi et al. in view of Roth before the use of thrombin/PGA felt to a wound site would enhance and/or facilitate the formation of fibrin network, instead of utilizing fibrinogen present in the plasma of a patient being treated with a reasonable expectation of success.

Furthermore, since the use of fibrinogen along with thrombin is well known in the art as a hemostatic composition, it would have been obvious to a person of ordinary skill in the art to try fibrinogen applied to the thrombin/PGA felt of Sugitachi et al. in view of Roth prior to the use of the felt to a wound site to stop bleeding with reasonable expectation of success in using the thrombin/PGA felt along with fibrinogen/Factor XIII of Greenawalt et al.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

With regard to the elastic property of the hemostatic material of the current

invention, the hemostatic felt made of PGA comprising thrombin taught by Sugitachi et al. in view of Roth would have inherently possessed the same property as the claimed invention because the material of the references is considered the same or substantially identical to the claimed invention.

M.P.E.P. § 2112 recites, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

With regard to the hemostatic kit of the current invention, Greenawalt et al. teach a hemostatic kit comprising multiple hemostatic compositions in a separate package. It is well known in the art hemostatic compositions are packaged in a form of kit as shown by Tisseel™ (see column 1, lines 20-22) and the teaching of Greenawlat et al. (see column 6, lines 51-59).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try to prepare the hemostatic materials of Sugitachi

et al. in view of Roth (i.e. thrombin/PGA felt) along with fibrinogen/Factor XIII of Tisseel™ disclosed by Greenawalt et al. in a format of a kit.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 9:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim, Ph.D.
Assistant Examiner
AU-1651

Leon B. Lankford, Jr.
Primary Examiner
AU-1651